

THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

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***In re:* VALSARTAN, LOSARTAN, AND IRBESARTAN  
PRODUCTS LIABILITY LITIGATION**

Master Docket No. 19-2875 (RBK/SAK)

**Order on Certification of  
Proposed Classes under FRCP  
Rule 23 and on Class  
Certification Expert Reports  
under FRE 702**

*This Document Applies to All Actions*

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**KUGLER**, United States District Judge:

**THIS MATTER HAVING COME BEFORE** the Court in this multidistrict litigation (“MDL” or “Valsartan MDL”) on several motions:

from All plaintiffs: a motion to certify two economic loss classes, each having a number of subclasses, as well as medical monitoring classes; and

from Third Party Payor [“TPP”] plaintiffs: a separate motion to certify a TPP economic loss class; and

from both defendants and plaintiffs seeking to preclude the reports of the class certification experts of the opposing party; and

this Order being accompanied by an Opinion of this date setting forth reasons therein for the rulings below,

**IT IS THEREFORE ORDERED**, regarding the motions to preclude, or strike, the reports of the parties’ class certification experts:

Plaintiffs’ Motion to Strike (ECF. No. 2043) New and Altered General Causation Opinions in the Report at ECF No. 2084, Exh. 2 of Michael Bottorff, PharmD is **GRANTED**, and in particular the following opinions of Dr. Bottorff are precluded:

1. “Oral doses at the levels detected in the generic valsartan at issue in this litigation are metabolized in the liver almost completely, **preventing** exposure to other tissues and organs” (Bottorff Class Certification Report at 48:761-762);
2. “NDMA/NDEA in valsartan **will not reach systemic circulation**” (Bottorff Class Certification Report at 47: 779); and
3. “DNA repair mechanisms in humans can be as much as 10 times higher than that in rats,

indicating a more active DNA repair in humans compared to rats” (Bottorff Class Cert. Report at 52:830-831).

Plaintiffs’ Motion to Preclude (ECF No. 2038) the Class Certification Report of David Chesney, BA, MSJ, is **GRANTED IN PART AND DENIED IN PART**. Only Mr. Chesney’s opinions on page 5 and immediately following in his Class Certification Report and which are limited to the issue of ZHP’s compliance with FDA current Good Manufacturing Practices and based solely on his review of ZHP documents have been considered here. The opinions and discussion in the rest of Mr. Chesney’s report have been precluded.

Plaintiffs’ Motion to Preclude (ECF No. 2047) the Class Certification Report of Jason Clevenger, PhD, is **GRANTED**.

Plaintiffs’ Motion to Preclude (ECF No. 2041) the Class Certification Report of Punam Keller, PhD, is **GRANTED IN PART AND DENIED IN PART**. Dr. Keller’s opinions on pages 30 to 45 in her Report have been precluded. Her opinions regarding scholarly literature on consumer health decision-making in pages 1-29 of her Report have been considered but only to the extent that these opinions are based on actual consumer surveys and real world consumer research.

Plaintiffs’ Motion to Preclude (ECF No. 2048) the Class Certification Report of Timothy Kosty, RPh, MBA, is **GRANTED IN PART AND DENIED IN PART**. The information and opinions in pages 49-99 of Mr. Kosty’s Report have been precluded. Mr. Kosty’s discussion of the workings of the U.S. pharmaceutical industry in pages 15-48 of his Class Certification Report has been considered.

Plaintiffs’ Motion to Preclude (ECF No. 2044) the Class Certification Report of William Lambert, PhD, is **GRANTED IN PART AND DENIED IN PART**. The following opinions in Dr. Lambert’s Report have been precluded:

- Dr. Lambert’s opinion about the “worthlessness” of the VCDs, couched in terms of bioequivalence, is an unqualified economics opinion,
- Any of Dr. Lambert’s opinions that the FDA’s Orange Book does or not establish / create manufacturer warranties. By excluding these opinions of Dr. Lambert’s, the Court is not expressly deciding one way or another whether the Orange Book creates manufacturer warranties; rather, the Court finds that Dr. Lambert is not a legal expert qualified to opine on such an issue.
- Any of Dr. Lambert’s opinions that plaintiffs failed to apply correct standards in determining for bioequivalence and pharmaceutical equivalence.
- Dr. Lambert’s opinions at ¶38 of his Class Certification Report; and
- Dr. Lambert’s opinions at ¶88 and ¶90 of his Class Certification Report.

Any other of Dr. Lambert’s opinions in his Report has been considered.

Plaintiffs' Motion to Preclude (ECF No. 2045) the Class Certification Report of Mark Robbins, PhD, JD is **DENIED**.

Plaintiffs' Motion to Preclude (ECF No. 2036) the Class Certification Report of Eric Sheinin, PhD is **GRANTED IN PART AND DENIED IN PART**. Paragraph 69, and paragraphs 79 to 102 in Dr. Sheinin's Report have been precluded. Paragraphs 25 to 68, and paragraphs 70-78 in Dr. Sheinin's Report have been considered but only as BACKGROUND information, and NOT as reliable expert opinion on class certification, liability, damages, etc. issues.

Plaintiffs' Motion to Preclude (ECF No. 2046) the Class Certification Report of Lauren Stiroh, PhD is **DENIED**.

Defendants' Motions (ECF Nos. 2040 ["General Motion"] and 2037 ["Wholesalers Motion"]) to Preclude the Class Certification Report of Rena Conti, PhD are **DENIED**.

Defendants' Motion to Preclude (ECF No. 2033) the Class Certification Report of Ron Najafi, PhD is **GRANTED**.

Defendants' motion to Preclude (ECF No. 2035) the Class Certification Report of John Quick, MBA, is **GRANTED IN PART AND DENIED IN PART**. Mr. Quick's opinions on pp. 6-7 of his Report regarding the terms "adulterated" and "misbranded" and whether the VCDs were "adulterated" and "misbranded" have been precluded; the other opinions in Mr. Quick's Report have been considered.

Defendants' Motion to Preclude (ECF No. 2034) the Class Certification Report of Kaliopi Panagos, PharmD and RPh, is **GRANTED IN PART AND DENIED IN PART**. Dr. Panagos's opinions at paragraphs 47, and 52-59 in her Report and in the Summary of Opinions on page 10, paragraphs: B, D, G – I have been precluded. Her opinions at paragraphs 1 to 46, 49-51 and 54 in her Report and in the Summary of Opinions on page 10, paragraphs: A, C, E, and F have been considered.

Defendants' Motion to Preclude (ECF No. 2024) the Class Certification Report of Edward Kaplan, MD, is **DENIED**.

Defendants' Motion to preclude the Class Certification Report of Zirui Song, MD, PhD is **GRANTED IN PART AND DENIED IN PART**. Dr. Song's his opinions on a methodology for calculating in a similar way the spend for medical monitoring services in pages 22 through 26 of his Report have been precluded. His discussion of background information in pages 8 through 21 in his Report has been considered.

**IT IS FURTHER ORDERED**, regarding plaintiffs' motions to certify certain classes:

Plaintiffs' Motion to certify the Consumer Economic Loss Class is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 3 herein;

Plaintiffs' Motion to certify the Third Party Payor Class is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 4 herein;

Plaintiffs' Motion to certify the *Rule 23(b)(3)* Class of Medical Monitoring as an Independent Claim [*"Rule 23(b)(3) IND MedMon Class"*] is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 7 herein;

Plaintiffs' Motion to certify the *Rule 23(b)(2)* Class of Medical Monitoring as an Independent Claim [*"Rule 23(b)(2) IND MedMon Class"*] is **DENIED without prejudice**. The Court **GRANTS** plaintiffs the option to re-seek class certification of this class by briefing on the specific estoppel effects this class may have on the other two certified Medical Monitoring classes;

Plaintiffs' Motion to certify the *Rule 23(b)(2)* Class of Medical Monitoring as a Remedy is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 7 herein; and

**IT IS FURTHER ORDERED:**

Defendants' Motion (ECF No. 206g) for leave to file instant sur-reply briefs in further opposition to plaintiffs motions for class certification, and Request for a class certification hearing is **DENIED** as made moot by this Opinion.

Dated: 8 February 2023

s/ Robert B. Kugler  
Honorable Robert B. Kugler  
United States District Judge